ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL–5130–5]

State of Tennessee, Metropolitan Government of Nashville and Davidson County; Request for Approval of Section 112(l) Authority for Hazardous Air Pollutants; Perchloroethylene Air Emission Standards From Dry Cleaning Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The State of Tennessee, Metropolitan Government of Nashville and Davidson County has applied for approval of its Regulation No. 4, Section 4–10, Regulations for Hazardous Air Pollutants; Perchloroethylene Air Emission Standards From Dry Cleaning Facilities under section 112(l) of the Clean Air Act (CAA). The Environmental Protection Agency (EPA) has reviewed the application and has made the decision that it satisfies all of the requirements necessary to qualify as a complete submittal. Thus, the Metropolitan Government of Nashville and Davidson County's Regulation No. 4, Section 4–10, should be implemented and enforced in place of EPA's 40 CFR part 63, subpart M.

DATES: This action will be effective on April 17, 1995, unless adverse or critical comments are received by March 31, 1995. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments should be sent concurrently to Douglas Neeley, Region 4 EPA, Air Programs Branch, 345 Courtland St. NE., Atlanta, GA 30365, Phone: (404) 347–3555 and to Mr. Paul Bontrager, Bureau of Environmental Health Services, Metropolitan Government of Nashville and Davidson County, 311 23rd Avenue, North, Nashville, Tennessee 37203, Phone: (615) 340–5653. Copies of Metropolitan Government of Nashville and Davidson County's submittal are available during normal business hours at the following addresses for inspection and copying:

Bureau of Environmental Health Services Metropolitan Government of Nashville and Davidson County, 311 23rd Avenue, North, Nashville, Tennessee;

U.S. EPA Headquarters Library, PM 211A, 401 M Street, SW., Washington, DC 20460, Phone: 202/382–5926; and

U.S. EPA Region 4, Regional Library, 345 Courtland St. NE., Atlanta, GA 30365, Phone number: (404) 347–3555, X6050.

FOR FURTHER INFORMATION CONTACT: Anthony Toney, Region 4 EPA, Air Programs Branch, 345 Courtland St. NE., Atlanta, GA 30365, Phone: (404) 347–3555, ext. 4200.

SUPPLEMENTARY INFORMATION:

A. Background

Section 112(l) of the Clean Air Act as amended in 1990, enables the EPA to approve state air toxic programs or rules to operate in place of the Federal air toxic program. Approval is granted by the EPA if the Agency finds that the state program or rule: (1) Is ''no less stringent'' than the corresponding Federal rule or program, (2) provides adequate authority and resources, (3) schedule for implementation and compliance is sufficiently expeditious, and (4) is otherwise in compliance with Federal guidance.

B. This is an initial request for delegation under the provisions of 40 CFR part 63, subpart E. No previous delegation of rules or regulations pursuant to title III of the Clean Air Act has been approved.

The changes from the federal rule, 40 CFR part 63, subpart M, are: (1) The lowering of a required emission rate; (2) An increase in the frequency of required monitoring; and (3) A decrease in the amount of time allowed for a source to come into compliance. These changes occur in subsections 4–10(b)(23); 4–10(c)(10); and 4–10(a) of the Metropolitan Government of Nashville and Davidson County's Regulation No. 4.

EPA is approving the Metropolitan Government of Nashville and Davidson County's air toxics Regulation No. 4, Section 4–10, as a direct final rule without prior proposal because the Agency views this as a noncontroversial delegation request and anticipates no adverse comments. If no adverse comments are received in response to this direct final rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent action. Any parties interested in commenting on this action should do so at this time.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of Title III of the Clean Air Act as amended, 42 U.S.C. 2399.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95–5024 Filed 2–28–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[PP1F3989, 1F3995/R2109; FRL–4938–3]

RIN 2070–AB78

Pesticide Tolerances for Fenbuconazole

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the fungicide fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, expressed as fenbuconazole, in or on the raw agricultural commodities pecans at 0.1 part per million (ppm) and stone fruit crop group (except plums and prunes) at 2.0 ppm. Rohm & Haas Co. submitted petitions requesting this regulation to establish maximum permissible levels for residues of the fungicide.

EFFECTIVE DATE: This regulation becomes effective on March 1, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 1F3989, 1F3995/R2109], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing request filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch Field Operations Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20450. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations

Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)- 305-5540.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of December 13, 1991 (56 FR 65080), which announced that Rohm and Haas, Agricultural Chemicals, Independence Mall West, Philadelphia, PA 19105, had submitted pesticide petition (PP) 1F3989 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR part 180 by establishing a regulation to permit residues of fenbuconazole (*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile) in or on stone fruit crop group and dried prunes at 2.0 ppm. In the **Federal Register** of March 2, 1994 (59 FR 9985), EPA announced that Rohm and Haas had amended the petition to propose amending 40 CFR part 180 to establish a tolerance of 2.0 ppm in or on stone fruit crop group for fenbuconazole, (*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile), and its metabolites *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone.

EPA issued a notice, published in the **Federal Register** of December 13, 1991 (56 FR 65081), which announced that Rohm and Haas had filed pesticide petition (PP) 1F3995 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR part 180 by establishing a regulation to permit residues of fenbuconazole (*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1-*H*-1,2,4-triazole)-1-propanenitrile) in or on pecans at 0.1 ppm. In the **Federal Register** of March 2, 1994 (59 FR 9985), EPA announced that Rohm and Haas had amended the petition to propose amending 40 CFR part 180 to establish a tolerance of 0.1 ppm in or on pecans for fenbuconazole (*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile), and its metabolites *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, and *alpha*-[2-[4-chlorophenyl)-2-oxoethyl]-*alpha*-phenyl-1*H*-1,2,4-triazole-1-propanenitrile. Rohm and Haas subsequently amended the petition to limit the stone fruit tolerances to stone fruit crop group (except plums and prunes). The Agency is editorially correcting the tolerance expression to read: combined residues of the fungicide, fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, expressed as fenbuconazole, in or on the raw agricultural commodities pecans at 0.1 part per million (ppm) and stone fruit crop group (except plums and prunes) at 2.0 ppm.

There were no comments or requests for referral to an advisory committee received in response to these notices of filing.

The scientific data submitted in the petitions and all other relevant material have been evaluated. The toxicology data considered in support of the tolerances include:

1. A rat acute oral study with an LD_{50} greater than 2 grams (g)/kilogram (kg).

2. A 13-week rat feeding study with a no-observed-effect-level (NOEL) of 20 ppm (1.3 milligrams(mg)/kg/day males and 1.5 mg/kg/day females) and a lowest-observed-effect-level (LOEL) of 80 ppm (5.1 mg/kg/day males and 6.3 mg/kg/day females), based on hepatotoxicity.

3. A 3-month mouse feeding study with a NOEL of 20 ppm (3.8 mg/kg/day males and 5.7 mg/kg/day females) and a LOEL of 60 ppm (11.1 mg/kg/day males and 17.6 mg/kg/day females) based on hepatotoxicity.

4. A 3-month dog feeding study with a NOEL of 100 ppm (3.3 mg/kg/day males and 3.5 mg/kg/day females) and LOEL of 400 ppm (13.3 mg/kg/day males and 14.0 mg/kg/day females), based on hepatocellular hypertrophy.

5. A 21-day rabbit dermal study with a NOEL greater than 1,000 mg/kg/day (limit dose).

6. A 78-week dietary carcinogenicity study in mice with a NOEL of 1.43 mg/kg/day and a LOEL of 28.6 mg/kg/day (males) and 92.9 mg/kg/day (females) based on hepatocellular enlargement and a greater incidence and severity of hepatocellular vacuolation. There was evidence of carcinogenicity based on the occurrence of increased trend for malignant liver tumors in males and an increase in benign and malignant liver tumors in females. The carcinogenic effects observed are discussed below.

7. A 24-month rat chronic feeding/carcinogenicity study with a NOEL of 40 ppm (3.03 mg/kg/day for females and 4.02 mg/kg/day for males) for systemic effects and a LEL of 800 ppm (30.62 mg/kg/day for males and 43.07 mg/kg/day for females) based on decreases in body weight gains and hepatocellular enlargement and vacuolization in females, and thyroid weight and histopathological changes in both sexes. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors in males. The carcinogenic effects observed are discussed below.

8. A 24-month male rat chronic feeding/carcinogenicity study with a NOEL of 800 ppm (30.41 mg/kg/day) and a LEL of 1,600 ppm (63.94 mg/kg/day) based on increased liver and thyroid weights and lesions. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors. The carcinogenic effects observed are discussed below.

9. A 1-year dog chronic feeding study with a NOEL of 150 ppm (3.75 mg/kg/day) and the LOEL, based on decreases in body weight gain and increased liver weight, of 1,200 ppm (30 mg/kg/day).

10. A two generation reproduction study in rats with a parental and reproductive NOEL of 4 mg/kg/day (80 ppm) and a LOEL of 40 mg/kg/day (800 ppm), based on decreased body weight and food consumption, increased number of dams not delivering viable or delivering nonviable offspring, and increases in adrenal and thyroid/parathyroid weights.

11. A developmental toxicity study in rabbits with a maternal NOEL of 10 mg/kg/day, and a developmental NOEL of 30 mg/kg/day, and a maternal LOEL of 60 mg/kg/day due to only 1/19 (5%) of the pregnant does producing a viable fetus and no developmental LOEL (greater than 30 mg/kg/day).

12. A developmental toxicity study in rats with a maternal NOEL and developmental NOEL of 30 mg/kg/day and an LEL of 75 mg/kg/day due to decrease in maternal body weight compared to controls and increase in early and late resorption with a decrease in number of live fetuses per dam.

13. No evidence of gene mutation was observed in a test for induction of gene mutation at the HGPRT locus in Chinese hamster ovary cells. No increase in the number of cells with aberrations or observations per cell were noted in an

in vivo cytogenetics assay using bone marrow from treated rats. No increase in unscheduled DNA synthesis in rat primary hepatocyte study was observed.

14. A rat metabolism study showed that radiolabeled fenbuconazole is rapidly absorbed, distributed, and excreted following oral administration in rats. Biliary excretion data indicated that systemic absorption of fenbuconazole was high for all dosing groups. The feces was the major route of excretion. Tissue distribution and bioaccumulation of fenbuconazole appeared to be minimal.

The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of fenbuconazole in mice and rats and has classified fenbuconazole as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** in 1986 (51 FR 33992, Sept. 24, 1986) and recommended that for the purpose of risk characterization a low-dose extrapolation model applied to the experimental animal tumor data should be used for quantification for human risk ($Q1^*$). This decision was based on the induction of thyroid follicular cell adenomas and/or combined adenomas-carcinomas in male rats in two studies, both by pair-wise comparison with controls and by trend analysis. The studies were combined for the purpose of deriving the $Q1^*$. The $Q1^*$ for fenbuconazole is 1.65×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

Based on assumptions that 100 percent of the pecan crop is treated and that residues are at the tolerance level, the upper-bound limit of the dietary carcinogenic risk for pecans is calculated in the range of 1 incidence in 100 million (9.0×10^{-9}). Based on assumption that stone fruit residues (except plums and prunes) are at the tolerance level and the limitation of production of the only fenbuconazole product registered under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) for use on stone fruit to 28,500 pounds of active ingredient per year (calculated to be equivalent to treating 12.8% of the total U.S acreage of apricots, cherries, nectarines, and peaches per year), the upper-bound limit of the dietary carcinogenic risk for stone fruit group except plums and prunes is calculated in the range of 1 incidence in 1 million (1×10^{-6}).

Processing studies for pecans and stone fruit other than plums and prunes are not required. Therefore, food/feed additive tolerances are not needed in conjunction with these uses.

Using the NOEL of 3.0 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100-fold safety factor, the Reference Dose (RfD) for systemic effects is 0.03 mg/kg/day. The theoretical maximum residue contribution (TMRC) from the proposed tolerances is 0.000604 mg/kg/day and utilizes 2 percent of the RfD for the overall U. S. population. For exposure of the most highly exposed subgroups in the population, nonnursing infants (less than 1 year old), the TMRC is 0.00516 mg/kg/day and utilizes 17 percent of the RfD.

The metabolism of fenbuconazole in plants is adequately understood. Due to a chemistry data gap for storage stability of fenbuconazole in other raw agricultural commodities [GLN 171-4(e)], EPA believes it is inappropriate to establish permanent tolerances for the uses of fenbuconazole at this time. However, based on apparent storage stability, EPA believes that the existing data support time-limited tolerances to December 31, 1998.

The nature of the residue in plants is adequately understood for the purposes of these time-limited tolerances. An analytical method, gas-liquid chromatography with a thermionic-specific detector with nitrogen selectivity, is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5232).

There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no livestock feed items associated with this action. The pesticide is considered useful for the purpose for which the tolerance is sought. Based on the information and data considered, the Agency has determined that the time-limited tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fees provided by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, and the requestor's contentions on each such issue, and a summary of the evidence relied upon by the objection (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve on or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: February 15, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By adding § 180.480, to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) Time-limited tolerances, to expire on December 31, 1998, are established for combined residues of the fungicide fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, expressed as fenbuconazole, in or on the following raw agricultural commodities:

Commodity	Parts per million
Pecans	0.1
Stone fruit crop group (except plums and prunes)	2.0

(b) Residues in these commodities not in excess of the established tolerance resulting from the uses described in paragraph (a) of this section remaining after expiration of the time-limited tolerance will not be considered to be actionable if the fungicide is applied during the term of and in accordance with the provisions of the above regulation.

[FR Doc. 95–5019 Filed 2–28–95; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[PP 4F4351/R2108; FRL–4938–1]

RIN 2070–AB78

Candida Oleophila Isolate I-182; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the post-harvest biological fungicide *Candida oleophila* isolate I-182. Ecogen, Inc., requested this tolerance exemption.

EFFECTIVE DATE: This regulation becomes effective on March 1, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4351/R2108], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: CS51L6, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8263.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of September 28, 1994 (59 FR 49396), which announced that Ecogen, Inc., 2005 Cabot Blvd. West, Langhorne, PA 19047, had submitted pesticide petition (PP) 4F4351 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosemtic Act (FFDCA), 21 U.S.C. 346a(d), establish an exemption from the requirement of a tolerance for residues of *Candida oleophila* isolate I-182 in or on all raw agricultural commodities. Errors in the September 28, 1994 notice of filing were corrected in the **Federal Register** of November 2, 1994 (59 FR 54911), to specify that *C. oleophila* isolate I-182 is a biological fungicide, not an insecticide, and that the area of title 40 of the Code of Federal Regulations (CFR) to be amended is 40 CFR part 180, not 40 CFR 180.1001(c) and (d).

There were no comments received in response to these notices of filing. The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance are summarized as follows:

Rats have been challenged with high doses of the pure preparations of *C. oleophila* by the oral, pulmonary, and interperitoneal routes of exposure. In each of these tests, the test animals survived to the end of the study without visible signs of toxicity or pathogenicity from the presence of *C. oleophila.* The test microbe was not isolated from any organs or tissues on day 3 in the oral and pulmonary studies and on day 7 in the interperitoneal injection study. These findings indicate that the test microbe was recognized by the immune system and cleared from the rats by the normal routes. In addition, the end-product formulation of *C. oleophila* was tested for dermal toxicity/irritation, eye irritation, and acute oral toxicity and showed no mortality or significant signs of toxicity.

Candida oleophila isolate I-182 is a microbial pesticide as defined by 40 CFR 158.65. The toxicity studies provided are sufficient to show that there are no foreseeable human or domestic health hazards likely to arise from the use of the product to control post-harvest decay in citrus and pome fruit.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition. Enforcement actions based on the level of residue found in a commodity are not expected. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request. *Candida oleophila* isolate I-182 is considered useful for the purposes for which the exemption from tolerance is sought. Based on the information and data considered, the Agency concludes